

Version with markings showing changes madeIn the specification

Page 1 has been amended read as follows:

TITLE OF THE INVENTION

Dosimeter for Sterilization with Ethylene Oxide

RELATED APPLICATION

This application claims priority of Provisional Application 60/138,064 filed 06 Aug 1999 and PCT/US00/15241 filed 02 June 2000

BACKGROUND OF THE INVENTION**1. FIELD OF THE INVENTION**

The present invention relates to a color changing chemical indicator device for monitoring sterilization of medical supplies with ethylene oxide. The device undergoes at least one color change with time, temperature and concentration of ethylene oxide.

2. BRIEF DESCRIPTION OF PRIOR ART

Products, such as medical supplies are sterilized to kill living organisms to an acceptable level. Direct testing for sterility is destructive and expensive and hence indirect testing methods are used. Biological indicators made from cultures, such as *Bacillus subtilis* spores, *Bacillus pumilus* spores and *Clostridium sporogenes* spores are used for monitoring the sterilization. However, chemical indicators are widely used because they are simple and inexpensive.

A wide variety of medical supplies are sterilized with materials and techniques, such as steam, plasma, high energy radiation and ethylene oxide. Ethylene oxide is abbreviated herein as ETO. It is essential to assure that the medical supply is sterilized. A number of indicators, dosimeters and monitors are proposed in the literature. They include biological and chemical indicators. The color changing chemical indicators are inexpensive and hence are widely used.

A number of patents have been issued on ethylene oxide indicators.

U.S. Pat. No. 3,852,034 describes an indicator for ethylene oxide which includes an amino substituted indicating compound, e.g., acid salts of amino substituted triphenylmethanes, diphenylmethanes, azines or xanthenes, which undergoes color change based on replacement of labile hydrogen in amino groups with hydroxyethyl and a buffering agent selected to provide an ionic dissociation equilibrium such that color change occurs only when sterilization has been effective.

TITLE OF THE INVENTION

Dosimeter for Sterilization with Ethylene Oxide

RELATED APPLICATION

This application claims priority of Provisional Application 80/138,084 filed 08 Aug 1999 and PCT/US00/15241 filed 02 June 2000

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An indicator composition for ethylene oxide gas comprising 4-(4-nitrobenzyl)pyridine, nitrocellulose, a basic substance, and, optionally, a blue coloring agent is disclosed in U.S. Pat. No. 4,094,842. The indicator composition, when exposed to ethylene oxide gas,